REMARKS

In the Office Action, claims 74, 75 and 77 are rejected under 35 U.S.C. §102 in view of U.S. Patent No. 4,443,441 (Galin I); claims 74-77 are rejected under 35 U.S.C. §103 in view of Galin I and U.S. Patent No. 5,612,027 (Galin II); and claims 74-77 are provisionally rejected for non-statutory obviousness-type double patenting. Applicant believes that the rejections are improper as detailed below.

At the outset, the Patent Office has rejected claims 74, 75 and 77 for alleged anticipation reasons in view of Galin I and further rejected these claims for alleged obviousness in view of Galin I and II. The anticipation rejection seems inconsistent with respect to the further alleged obviousness rejection which was alleged in view of additional art (e.g., Galin II). Therefore, Applicant believes that the anticipation rejection is improper at least in view of same.

In any event, Applicant does not agree with the Patent Office position with respect to the cited art. While Galin I generally describes an ophthalmic solution that contains alpha-adrenergic blocking agents and further provides a list of six possible agents, the preferred and only working example is directed to a solution that contains thymoxamine, and thus Galin I fails to recognize the benefits of the claimed ophthalmic night vision formulation with phentolamine. Indeed, the improved effect of a phentolamine-based solution on night vision as claimed, let alone phentolamine in an ophthalmic artificial tear solution as further defined in claim 76, should not be deemed an inherent property of the ophthalmic solution described in Galin I. Again, the preferred solution in Galin I is thymoxamine in purified water as detailed in the only working example. Moreover, Applicant has conducted experiments as detailed in the specification which demonstrate the enhanced benefits to vision in dim light associated with the claimed phentolamine-based formulation as compared to other alpha-1 antagonist-based formulations. See, Applicant's Specification, Examples 1 and 2 and Tables 1 and 2, beginning on page 24. Such unexpected results are further supported by the Affidavit of Gerald Horn, M.D. that was previously submitted in this case. Therefore, Applicant does not believe that Galin I provides sufficient teaching to render unpatentable the phentolamine-based ophthalmic solution that improves night vision as defined in presently pending claims 74-77.

Even assuming properly combinable, Galin II does not remedy the deficiencies of Galin I. At the outset, Galin II was merely relied on for its alleged teaching regarding "the use of

viscoelastic agents (artificial tear) in combination with mydriatic and miotic agents in ophthalmic solutions" (see, Office Action, p. 3). Further, the Patent Office has mischaracterized Galin II.

For example, Galin II is directed to "compositions which may be used to maintain structural integrity of the anterior chamber of the eye and to provide sustained release of a miotic or mydriatic agent." See, Galin II, col. 2, lines 5-8. "In order to maintain the structural integrity of the anterior chamber of the eye, the compositions of [Galin II] must be sufficiently viscous such as to prevent the chamber from collapsing during surgical manipulation...[and] sufficiently fluid to permit their introduction into the anterior chamber by injection or extrusion...where the concentrations of viscoelastic polymer are preferably between about 10 mg/ml and 30 mg/ml..." See, Galin II, col. 7, lines 29-36. Clearly, the "viscous" composition in Galin II which is introduced into the anterior chamber by injection or extrusion contrasts with the claimed ophthalmic formulation that includes a phentolamine-based active compound in a sterile aqueous carrier, such as an artificial tear solution to "promote good wettability and spread" for administration to the corneal surface of the eye as further embodied in claim 76 and supported in the specification, for example, at paragraphs [0140] to [0146]. For at least these reasons, Applicant respectfully submits that the anticipation and obviousness rejections should be withdrawn.

Further, claims 74-77 appear to be provisionally rejected under 35 U.S.C. §101 in view of copending application nos. 10/799,299 and 10/867,144. Considering this rejection is provisional, Applicant elects to address this rejection upon allowance of at least one of the present application and the co-pending patent applications at issue to the extent even applicable at that time, and thus this response should be considered responsive to the provisional rejections at this stage.

Accordingly, Applicant respectfully submit that the present application is in condition for allowance. The Commissioner is hereby authorized to charge deposit account 02-1818 for any fees which are due and owing.

Respectfully submitted,
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